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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,745	03/24/2004	James A. Goldstein	60018300-0012	5417

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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/807,745

Applicant(s)

GOLDSTEIN, JAMES A.

Examiner

Patricia C. Mallari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,9-11,22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,12-16,21,24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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DETAILED ACTION

This is a non-final Office action. Claims originally withdrawn from prosecution have been rejoined in light of arguments presented by the applicant. See below for details.

Election/Restrictions

The applicant requests that claims 1-6 and 21-25 be examined because the embodiment of figure 5 includes one in which the sensor is mounted on the support via the restraint. The examiner agrees with this assessment of figure 5 and claims 1, 4-6, 21, 24, and 25 are no longer withdrawn and belong to the elected species. The applicant further argues that the embodiment of figure 5 includes a support having a surface for receiving at least a portion of the patient's limb. However, the embodiment of figures 5-7 does not include one in which the surface has a contour disclosed as generally corresponding to a portion of an arm or hand of the patient's limb. Therefore, claims 2, 3, 22, and 23 remain withdrawn

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 4-6, 21, 24, and 25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites "upward facing surface upon which at least a portion of the patient's limb is rested". Claim 21

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also recites, "an upward facing surface upon which at least a portion of the patient's limb is rested to support the limb". The human body and any part thereof is non-statutory subject matter which cannot be positively claimed. In order to overcome this rejection, for example, the recited limitation of claim 1 should be amended to read "an upward facing surface upon which at least a portion of the patient's limb is adapted to be rested".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 8, 12-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 7 and 15 state that the support receives at least a portion of the limb to support the limb independent of the patient. However, the instant specification states that the support supports the limb, the limb being a portion of the patient. The specification therefore lacks written support for a support that receives a portion of the limb to support the limb independent of the patient, since any support of any portion of the patient must inherently be dependent upon the patient.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 8, 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7 and 15 state that support is for receiving at least a portion of the limb to support the limb independent of the patient. However, it is unclear how a support can support the limb of the patient independent of the patient, when the limb is a portion of the patient. By supporting the limb, the support is inherently occurring dependent upon the patient. For the purpose of this examination only and to the best understanding of the examiner, the limitation "to support the limb independent of the patient to limit movement of the limb during the procedure regardless of movement of other portions of the patient" is being interpreted as "to support the limb during the procedure regardless of movement of the other portions of the patient". The applicant is required to amend the recited limitations in any case.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 8, 12-16, 21, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,516,289 to David. David teaches a support apparatus for restraining movement of at least a portion of a patient's limb. The apparatus comprises a support 12 for receiving at least a portion of the limb via a restraint 10 mounted on the support. The support provides support to the limb regardless of movement of other portions of the patient. The restraint includes a sensor 30 adapted to communicate with the patient's limb for measuring a physiological parameter when the limb is received by the restraint (see entire document, especially fig. 3, 5; col. 3, lines 4-37 of David).

It is noted that the support 12 of David is fully capable of being hung from a location other than the neck of a user, wherein such an alternate location would not alter the ability of the apparatus as a whole to sense physiological parameters from a user whose arm is inserted into the glove/sleeve 10. Therefore the support of David is for supporting the limb regardless of movement of other portions of the patient.

As to the limitation "during a procedure" the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art of record since David teaches all of the claimed structural elements and their recited relationships. The apparatus of David may certainly be used during a procedure, as claimed.

Regarding claim 8, the sensor is an EKG sensor (see entire document, especially col. 3, lines 28-34 of David).

Regarding claim 12, the restraint comprises a glove adapted to receive at least a portion of a hand of the patient's limb (see entire document, especially fig. 2; col. 3, lines 8-10 of David).

Regarding claims 13 and 15, the glove comprises a first portion adapted to receive at least a portion of a first digit of the hand and a second portion separate from the first portion adapted to receive at least a portion of a second digit (see entire document, especially figs. 2 & 3 of David).

Regarding claims 14 and 16, the glove includes a sleeve adapted receive at least an arm of the limb and for measuring the physiological parameter on the arm (see entire document, especially figs. 2 & 3 of David).

Regarding claims 21, 24, and 25, David teaches a support apparatus for supporting at least a portion of a patient's limb during a procedure. The apparatus comprises a support 12 having an upward facing surface upon which at least a portion of the patient's limb is rested. A sensor 30 is mounted on the support via the restraint 10 which is attached to the support 12. The sensor includes a measuring region facing away from the support surface for engaging the patient's limb when received by the support for measuring a physiological parameter of the patient, wherein the sensor 30 contacts the skin of the arm placed in the restraint 10 (see entire document, especially figs. 3, 5; col. 3, lines 4-37 of David). Therefore, when the restraint and support are attached as shown in figure 5, the active surface of the sensor is facing away from the upward facing surface of the support

As to the language "during a procedure", the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since David, teaches all of the claimed structural limitations and their recited relationships. The apparatus of David is certainly capable of being used during a procedure as claimed.

Regarding claim 24, a restraint member 10 is provided, wherein the restraint 10 is capable of restraining movement of at least a portion of the patient's limb (see entire document, especially figs. 2 & 5 of David).

Regarding claim 25, the sensor is an electrocardiograph sensor (see entire document, especially col. 3, lines 28-34 of David).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,516,289 to David in view of US Patent NO. 4,889,131 to Salem et al. David teaches a support apparatus for supporting at least a portion of a patient's limb during a procedure. The apparatus comprises a support 12 having an upward facing surface upon which at least a portion of the patient's limb is rested. A sensor 15

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is mounted on the support such that the sensor is at least partially attached to the support, said sensor being adapted to communicate with the patient's limb for measuring a physiological parameter of the patient on the limb when the limb is supported by the support (see entire document, especially fig. 5; col. 3, lines 14-15 of David). David is silent as to how the electrode is attached to the substrate/support. However, Salem teaches EKG electrodes attached to a substrate or support by snap connectors (see entire document, especially fig. 4, col. 4, lines 1-5 of Salem) such that no adhesive is used. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the connectors of Salem as those of David, since David teaches the electrode connected to the support, and Salem teaches an appropriate means for attaching such electrodes to a support.

As to the language "during a procedure", the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since David, as modified, teaches all of the claimed structural limitations and their recited relationships. The apparatus of David, as modified, is certainly capable of being used during a procedure as claimed.

Regarding claim 4, the sensor is mounted on the support generally adjacent the surface so the sensor is adapted to communicate with a portion of the patient's limb in contact with the surface (see entire document, especially fig. 5 of David).

Regarding claim 5, a restraint member 10 is provided, wherein the restraint 10 is capable of restraining movement of at least a portion of the patient's limb (see entire document, especially figs. 2 & 5 of David).

Regarding claim 6, the sensor is an electrocardiograph sensor (see entire document, especially col. 3, lines 14-15 of David).

Response to Arguments

Applicant's arguments filed 11/28/06 have been fully considered but they are not persuasive.

With respect to claims 7, 8, 12-16, the applicant argues that David does not support the limb independent of the patient as required by the claim. However, as noted in the rejections under 35 U.S.C. 112 above, it is unclear how support of a portion a patient's limb can be independent of the patient, since it inherently involves the portion of the patient's limb. In view of the lack of clarity, the examiner has provided an interpretation of applicants' intent in the rejection set forth above. All claims bearing similar language have been interpreted accordingly.

The applicant further states that the sling of David supports the limb from the patient's neck so the limb moves with the patient's neck and movement of the limb is not limited regardless of movement of other portions of the patient. Claim 7 states "a support *for* receiving at least a portion of the patient's limb thereon to support the limb independent of the patient to limit movement of the limb during the procedure regardless of movement of other portions of the patient", wherein the emphasis is added to show that the function of the support is merely "intended use" language, which cannot be relied upon to define over the prior art since David teaches all of the claimed structural limitations and their recited relationships. The apparatus of David is certainly *capable* of being used for receiving the limb in such a manner. For example, as set

forth in the rejection under 35 U.S.C. 102(b) above, the sling is certainly capable of being hung from something other than the patient's neck, wherein this alternate location of the sling fails to affect the ability of the apparatus as a whole to sense information from the limb of the patient and further provides support and limited movement regardless of movement of other portions of the patient, as claimed.

Therefore, the rejection stands.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

for
pcm

Robert L. Nasser
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